

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, <u>et al.</u> , <u>ex rel.</u> ,	:	
CHARLES STRUNCK, <u>et al.</u> ,	:	
	:	
Plaintiffs,	:	
	:	Civil Action No. 12-CV-0175
v.	:	
	:	
MALLINCKRODT ARD LLC	:	
(f/k/a Mallinckrodt ARD, Inc.;	:	
f/k/a Questcor Pharmaceuticals, Inc.),	:	
	:	
Defendant.	:	
	:	

**ANSWER OF DEFENDANT MALLINCKRODT ARD LLC TO THE
UNITED STATES' COMPLAINT IN INTERVENTION**

Defendant Mallinckrodt ARD LLC, formerly known as Questcor Pharmaceuticals, Inc., (“Questcor”), by and through its undersigned counsel, hereby responds to the United States’ Complaint in Intervention (the “Complaint”) as follows:

ALLEGATIONS MADE IN HEADINGS

The headings contained in the Complaint are not allegations and therefore do not require responses. To the extent a response is required, Questcor denies all allegations contained in the headings contained in the Complaint.

NUMBERED PARAGRAPHS

1. Paragraph 1 contains no factual allegations to which a responsive pleading is required. To the extent a response is required, Questcor admits that the United States of America (“United States”) purports to bring an action pursuant to the False Claims Act (“FCA”), but denies that Questcor violated the FCA and denies that any entity was damaged.

2. Questcor admits that Mallinckrodt ARD LLC was formerly known as Mallinckrodt ARD, Inc. and Questcor Pharmaceuticals, Inc. Except as so admitted, Questcor denies the allegations contained in Paragraph 2.

3. Questcor admits that Acthar[®] was approved by the U.S. Food and Drug Administration (“FDA”) in 1952. Questcor further admits that it acquired worldwide rights to sell and manufacture Acthar. Except as so admitted, Questcor denies the allegations in Paragraph 3.

4. Denied.

5. Denied.

6. Denied.

7. Denied.

8. Paragraph 8 states legal conclusions as to which no response is required.

9. Paragraph 9 states legal conclusions as to which no response is required.

10. Paragraph 10 states legal conclusions as to which no response is required.

11. Paragraph 11 contains no factual allegations to which a responsive pleading is required. To the extent a response is required, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 11 and on that basis denies the same.

12. Questcor admits that Charles Strunck was employed by Questcor from September 2010 until August 2011 as an Acthar sales specialist, and that Lisa Pratta was employed by Questcor from September 2010 until June 2017 as an Acthar sales specialist in New Jersey. Questcor further admits that it was named as a defendant in a lawsuit entitled *United States, et al., ex. rel. Strunck v. Questcor Pharm., Inc.*, filed in the United States District Court for the Eastern District of Pennsylvania. Except as so admitted, Questcor is without knowledge or

information sufficient to admit or deny the allegations in Paragraph 12 and on that basis denies the same. Questcor further denies that Strunck and Pratta qualify as relators within the meaning of the FCA.

13. Questcor admits that Scott Clark was employed by Questcor from September 2010 until 2012 as an Acthar sales specialist in the State of Oregon. Questcor further admits that it was named as a defendant in a lawsuit entitled *United States, et al., ex. rel. Clark v. Questcor Pharm., Inc.*, filed in the United States District Court for the Eastern District of Pennsylvania. Questcor denies that Scott Clark's employment ended in June 2012. Except as so admitted and denied, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 13 and on that basis denies the same. Questcor further denies that Clark qualifies as a relator within the meaning of the FCA.

14. Admitted.

15. Questcor admits that Mallinckrodt ARD LLC is a subsidiary of Mallinckrodt plc, an Irish public limited company. Questcor further admits that it entered into an Agreement and Plan of Merger with Mallinckrodt plc on April 5, 2014, and that Mallinckrodt plc acquired Questcor on August 14, 2014. Except as so admitted, Questcor denies the allegations in Paragraph 15.

16. Questcor admits that it is a wholly owned indirect subsidiary of Mallinckrodt plc, that it continued to market Acthar following the merger, and that it changed its name to Mallinckrodt ARD, Inc. on July 27, 2015. Except as so admitted, Questcor denies the allegations in Paragraph 16.

17. Admitted.

18. Questcor admits that it has marketed Acthar in the United States. Except as so admitted, Questcor denies the allegations in Paragraph 18.

19. Paragraph 19 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States' characterization of the same.

20. Questcor admits that Medicare is administered by the Centers for Medicare & Medicaid Services ("CMS") and that CMS is part of the United States Department of Health and Human Services ("HHS"). Except as so admitted, Questcor denies the allegations in Paragraph 20.

21. Paragraph 21 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced legislation for its actual language and complete contents and denies the United States' characterization of the same.

22. Paragraph 22 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced Medicare regulations for their actual language and complete contents and denies the United States' characterization of the same.

23. Paragraph 23 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced Medicare regulations for their actual language and complete contents and denies the United States' characterization of the same.

24. Paragraph 24 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced Medicare regulations for their actual language and complete contents and denies the United States' characterization of the same.

25. Paragraph 25 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced legislation for its actual language and complete contents and denies the United States' characterization of the same.

26. Paragraph 26 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced legislation for its actual language and complete contents and denies the United States' characterization of the same.

27. Paragraph 27 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the Medicare regulations for their actual language and complete contents and denies the United States' characterization of the same.

28. Paragraph 28 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the Medicare regulations for their actual language and complete contents and denies the United States' characterization of the same.

29. Paragraph 29 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced legislation

for its actual language and complete contents and denies the United States' characterization of the same.

30. Questcor respectfully refers the Court to the referenced HHS Office of the Inspector General ("HHS-OIG") guidance for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 30 on the ground that they are broad generalizations that do not fully and accurately represent the matters they purport to describe.

31. Paragraph 31 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States' characterization of the same.

32. Paragraph 32 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States' characterization of the same.

33. Paragraph 33 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States' characterization of the same.

34. Paragraph 34 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States' characterization of the same.

35. Questcor respectfully refers the Court to the Anti-Kickback Statute (“AKS”) and its legislative history for their actual language and complete contents and denies the United States’ characterization of the same.

36. Paragraph 36 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced legislation for its actual language and complete contents and denies the United States’ characterization of the same.

37. Paragraph 37 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States’ characterization of the same.

38. Paragraph 38 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statutes for their actual language and complete contents and denies the United States’ characterization of the same.

39. Paragraph 39 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States’ characterization of the same.

40. Paragraph 40 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States’ characterization of the same.

41. Paragraph 41 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced legislation for its actual language and complete contents and denies the United States' characterization of the same.

42. Paragraph 42 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States' characterization of the same.

43. Paragraph 43 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States' characterization of the same.

44. Paragraph 44 states legal conclusions as to which no response is required. To the extent a response is required, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 44 and on that basis denies the same.

45. Denied.

46. Denied.

47. Questcor admits that multiple sclerosis ("MS") is a potentially disabling disease of the brain and spinal cord (central nervous system) in which the immune system attacks the protective sheath (myelin) that covers nerve fibers. Questcor further admits that signs and symptoms of MS vary widely and depend on the amount of nerve damage and which nerves are affected. Except as so stated, Questcor denies the allegations in Paragraph 47.

48. Denied.

49. Questcor admits that Acthar is FDA-approved for the treatment of acute exacerbations of MS in adults. Except as so admitted, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 49 and on that basis denies the same.

50. Questcor admits that Acthar is FDA-approved for the treatment of acute exacerbations of MS in adults. Except as so admitted, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 50 and on that basis denies the same.

51. Admitted.

52. Denied.

53. Denied.

54. Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 54 and on that basis denies the same.

55. Questcor admits that rheumatoid arthritis (“RA”) is an inflammatory autoimmune disorder in which the body’s immune system mistakenly attacks the body’s tissues, including the joints. Except as so admitted, Questcor denies the allegations in Paragraph 55.

56. Denied.

57. Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 57 and on that basis denies the same.

58. Questcor admits that Acthar is a naturally sourced complex mixture of adrenocorticotrophic hormone (ACTH) analogs and other pituitary peptides and that a major component in the formulated mixture is N-25 deamidated porcine ACTH (1-39). Except as so admitted, Questcor denies the allegations in Paragraph 58.

59. Questcor admits that Acthar was developed by Armour Pharmaceutical Company, that Acthar was approved for certain uses in 1952 by the FDA, and that Acthar's active ingredient is extracted from porcine pituitary glands. Except as so admitted, Questcor denies the allegations in Paragraph 59.

60. Questcor respectfully refers the Court to Acthar's current FDA-approved label for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 60.

61. Questcor admits that Acthar's current FDA-approved label contains the information referenced in Paragraph 61 and respectfully refers the Court to Acthar's current FDA-approved label for its actual language and complete contents. Except as so admitted, Questcor denies the allegations in Paragraph 61.

62. Questcor admits that Acthar's current FDA-approved label contains the information referenced in Paragraph 62 and respectfully refers the Court to Acthar's current FDA-approved label for its actual language and complete contents. Except as so admitted, Questcor denies the allegations in Paragraph 62.

63. Questcor admits that Acthar's current FDA-approved label contains the information referenced in Paragraph 63 and respectfully refers the Court to Acthar's current FDA-approved label for its actual language and complete contents. Except as so admitted, Questcor denies the allegations in Paragraph 63.

64. Admitted.

65. Questcor admits that it acquired worldwide rights to sell and manufacture Acthar from another drug company, Aventis Pharmaceuticals, Inc. Except as so admitted, Questcor denies the allegations in Paragraph 65.

66. Questcor respectfully refers to the Court to Questcor's Form 10-K for the fiscal year ended December 31, 2006 for its actual language and complete contents. Except as so stated, Questcor denies the allegations in Paragraph 66.

67. Questcor denies the allegations contained in Paragraph 67 on the ground that they are broad generalizations that do not fully and accurately represent the matters they purport to describe.

68. Questcor admits that it adopted an orphan pricing strategy for Acthar. Except as so admitted, Questcor denies the allegations in Paragraph 68.

69. Denied.

70. Denied.

71. Denied.

72. Questcor denies the allegations contained in Paragraph 72 on the ground that they are broad generalizations that do not fully and accurately represent the matters they purport to describe and respectfully refers to the Court to Questcor's Form 10-K for the fiscal year ended December 31, 2007 for its actual language and complete contents.

73. Denied.

74. Denied.

75. Denied.

76. Questcor admits that CDF is headquartered in Plano, Texas. Except as so admitted, Questcor denies the allegations in Paragraph 76.

77. Denied.

78. Denied.

79. Denied.

80. Questcor admits that it established a pilot MS sales force in 2008. Except as so admitted, Questcor denies the allegations in Paragraph 80.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Questcor admits that it made donations to a foundation called the National Organization for Rare Disorders (“NORD”). Except as so admitted, Questcor denies the allegations contained in Paragraph 85.

86. Denied.

87. Denied.

88. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States’ characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 88.

89. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States’ characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 89.

90. Questcor admits that CDF made a presentation to Questcor employees on or about June 1, 2010. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States’ characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 90.

91. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 91.

92. Questcor admits that CDF established an MS Acute Exacerbation Fund and an Acthar "Private Fund." Except as so admitted, Questcor denies the allegations in Paragraph 92 and footnote 1.

93. Questcor respectfully refers the Court to the referenced term sheet for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 93.

94. Questcor admits that it sent an executed copy of the donation agreement for the MS Acute Exacerbation Fund to CDF on or about July 14, 2010.

95. Questcor denies the allegations in Paragraph 95 and respectfully refers the Court to the referenced MS Acute Exacerbation Fund agreement for its actual language and complete contents and denies the United States' characterization of the same.

96. Questcor denies the allegations in Paragraph 96 and respectfully refers the Court to the referenced MS Acute Exacerbation Fund agreement for its actual language and complete contents and denies the United States' characterization of the same.

97. Questcor denies the allegations in Paragraph 97 and respectfully refers the Court to the referenced MS Acute Exacerbation Fund agreement for its actual language and complete contents and denies the United States' characterization of the same.

98. Questcor denies the allegations in Paragraph 98 and respectfully refers the Court to the referenced communications for their actual language and complete contents and denies the United States' characterization of the same.

99. Questcor admits that, on July 15, 2010, Questcor's COO approved a donation from Questcor to CDF in the amount of \$150,000 that was made by wire transfer. Except as so admitted, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 99 and on that basis denies the same.

100. Questcor admits that the Acthar Support and Access Program included a call-center and received referrals from physician offices and patients. Except as so admitted, Questcor denies the allegations in Paragraph 100.

101. Denied.

102. Denied.

103. Questcor respectfully refers the Court to the referenced analysis for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 103.

104. Denied.

105. Denied.

106. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 106.

107. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 107.

108. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 108.

109. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 109.

110. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 110.

111. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 111.

112. Questcor respectfully refers the Court to the referenced emails for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 112.

113. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 113.

114. Questcor admits that its COO signed a Lupus Exacerbation donation agreement dated October 31, 2011. Except as so admitted, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 114 and on that basis denies the same.

115. Questcor denies the allegations in Paragraph 115 and respectfully refers the Court to the referenced Lupus Exacerbation Fund agreement for its actual language and complete contents and denies the United States' characterization of the same.

116. Questcor admits that it wired a \$25,000 donation to CDF on November 2, 2011. Except as so admitted, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 116 and on that basis denies the same.

117. Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 117 and on that basis denies the same.

118. Questcor admits that the FDA approved Acthar for maintenance therapy in selected cases of systemic lupus erythematosus. Except as so admitted, Questcor denies the allegations in Paragraph 118.

119. Questcor respectfully refers the Court to the referenced document for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 119.

120. Questcor is without knowledge or information sufficient to admit or deny the allegations in the second sentence of Paragraph 120 and on that basis denies the same. Except as so stated, Questcor denies the allegations in Paragraph 120.

121. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 121.

122. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 122 and on that basis denies the same.

123. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 123.

124. Questcor respectfully refers the Court to the referenced emails for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 124.

125. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 125.

126. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 126 and on that basis denies the same.

127. Denied.

128. Denied.

129. Questcor admits that it sent an executed MS Acute Exacerbation Fund contract to CDF in July 2010. Questcor further refers the Court to the referenced emails for their actual language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 129.

130. Questcor denies the allegations contained in Paragraph 130 on the ground that they are broad generalizations that do not fully and accurately represent the matters they purport to describe and respectfully refers the Court to the document quoted in Paragraph 130

for its actual language and complete contents. Except as so stated, Questcor denies the allegations in Paragraph 130.

131. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 131.

132. Questcor denies the allegations in the first sentence of Paragraph 132. Questcor is without knowledge or information sufficient to admit or deny the allegations in the second sentence of Paragraph 132 and on that basis denies the same.

133. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 133.

134. Questcor admits that NORD operated a patient assistance program that offered Acthar free of charge to patients who met certain financial criteria. Questcor states that it is without information sufficient to admit or deny the allegation in the second sentence of Paragraph 134. Except as so admitted and stated, Questcor denies the allegations in Paragraph 134.

135. Questcor respectfully refers the Court to the referenced document for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 135.

136. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 136.

137. Denied.

138. Questcor respectfully refers the Court to the referenced document for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 138.

139. Questcor respectfully refers the Court to the referenced training slides for their actual language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 139.

140. Questcor respectfully refers the Court to the referenced email for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 140.

141. Questcor admits that it commissioned a study of neurologists. Questcor respectfully refers the Court to the referenced study documents for their actual language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 141.

142. Questcor respectfully refers the Court to the referenced sales plan for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 142.

143. Questcor respectfully refers the Court to the referenced emails for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 143.

144. Questcor respectfully refers the Court to the referenced emails for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 144.

145. Denied.

146. Denied.

147. Questcor admits that it received Program Reports. Questcor respectfully refers the Court to the referenced Program Reports for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 147.

148. Questcor is without knowledge or information sufficient to admit or deny the allegations in the first sentence of Paragraph 148 and on that basis denies the same. Questcor denies the allegations in the second sentence of Paragraph 148.

149. Questcor respectfully refers the Court to the referenced emails for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 149.

150. Questcor admits that it received "Case Review" reports from the BioSolutia Consultant. Questcor respectfully refers the Court to the referenced "Case Review" reports for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 150.

151. Denied.

152. Questcor respectfully refers the Court to the referenced emails for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 152.

153. Questcor admits that it entered into a Service Agreement Amendment with CDF on September 1, 2012. Questcor respectfully refers the Court to the referenced Service Agreement Amendment for its actual language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the

allegations in Paragraph 153 and footnote 2 on the ground that they are broad generalizations that do not fully and accurately represent the matters they purport to describe.

154. Questcor admits that, in December 2013, CDF informed Questcor that it decided to close, among others, the MS Acute Exacerbation Fund, the Lupus Exacerbation Fund, and the RA Exacerbation Fund, but that it would continue to assist already-enrolled patients for another year. Questcor further admits that it made donations to CDF in 2014. Except as so admitted, Questcor denies the allegations in Paragraph 154.

155. Denied.

156. Denied.

157. Questcor respectfully refers the Court to the referenced business plan for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 157.

158. Questcor respectfully refers the Court to the referenced presentation for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 158.

159. Denied.

160. Questcor respectfully refers the Court to Questcor's Form 10-K for the year ending December 31, 2013 for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 160.

161. Denied.

162. Paragraph 162 contains legal conclusions to which no response is required. To the extent a response is required, Questcor admits that it has knowledge and understanding of

the AKS and the FCA and that it trained its employees on these laws. Except as so admitted, Questcor denies the allegations contained in Paragraph 162 on the ground that they are broad generalizations that do not fully and accurately represent the matters they purport to describe.

163. Questcor respectfully refers the Court to the referenced compliance training documents for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 163.

164. Questcor respectfully refers the Court to the referenced corporate policies for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations contained in Paragraph 164.

165. Questcor admits that its Reimbursement Assistance policy contains the statement quoted in Paragraph 165 and respectfully refers the Court to the referenced policy for its actual language and complete contents.

166. Questcor respectfully refers the Court to the referenced Reimbursement Assistance policy for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor denies the allegations in Paragraph 166.

167. Questcor admits that it trained its employees on the AKS and the FCA. Questcor respectfully refers the Court to the referenced emails for their actual language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 167.

168. Questcor admits that it trained its employees on the AKS and the FCA. Questcor respectfully refers the Court to the referenced publications and emails for their actual

language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 168.

169. Denied.

170. Paragraph 170 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced legislation for its actual language and complete contents and denies the United States' characterization of the same.

171. Questcor admits that HHS-OIG has issued industry wide guidance since at least 2005. Questcor respectfully refers the Court to such guidance for its actual language and complete contents and denies the United States' characterization of the same.

172. Questcor admits that HHS-OIG has issued industry wide guidance since at least 2005. Questcor respectfully refers the Court to such guidance for its actual language and complete contents and denies the United States' characterization of the same.

173. Questcor admits that HHS-OIG has issued industry wide guidance since at least 2005. Questcor respectfully refers the Court to such guidance for its actual language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 173.

174. Questcor admits that HHS-OIG has issued industry wide guidance since at least 2005. Questcor respectfully refers the Court to such guidance for its actual language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 174 and in footnote 3.

175. Questcor admits that HHS-OIG has issued industry wide guidance since at least 2005. Questcor respectfully refers the Court to such guidance for its actual language and

complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 175.

176. Questcor admits that HHS-OIG has issued industry wide guidance since at least 2005. Questcor respectfully refers the Court to such guidance for its actual language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 176.

177. Questcor admits that HHS-OIG has issued industry wide guidance since at least 2005. Questcor respectfully refers the Court to such guidance for its actual language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 177.

178. Questcor admits that HHS-OIG has issued industry wide guidance since at least 2005. Questcor respectfully refers the Court to such guidance, including to Advisory Opinion 06-10, for its actual language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 178.

179. Questcor admits that HHS-OIG has issued industry wide guidance since at least 2005 and that Questcor had a copy of Advisory Opinion 06-10. Questcor respectfully refers the Court to the referenced guidance and donation agreements for their actual language and complete contents and denies the United States' characterization of the same. Except as so admitted and stated, Questcor denies the allegations in Paragraph 179.

180. Denied.

181. Denied.

182. Denied.

183. Denied.

184. Denied.

185. Denied.

186. Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 186, which appear to describe the process that may apply where non-specialty pharmaceutical products are prescribed to a Medicare Part D beneficiary, and on that basis denies the same.

187. Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 187 and on that basis denies the same.

188. Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 188 and on that basis denies the same.

189. Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 189 and on that basis denies the same.

190. Questcor respectfully refers the Court to the referenced regulation for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 190 and on that basis denies the same.

191. Questcor respectfully refers the Court to the referenced regulation for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 191 and footnote 4 and on that basis denies the same.

192. Paragraph 192 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced

legislation for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 192 and on that basis denies the same.

193. Paragraph 193 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced legislation for its actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 193 and on that basis denies the same.

194. Paragraph 194 states legal conclusions as to which no response is required. To the extent a response is required, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 194 and on that basis denies the same.

195. Paragraph 195 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States' characterization of the same.

196. Paragraph 196 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute for its actual language and complete contents and denies the United States' characterization of the same.

197. Paragraph 197 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the referenced statute

for its actual language and complete contents and denies the United States' characterization of the same.

198. Paragraph 198 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the relevant HHS-OIG guidance for its actual language and complete contents and denies the United States' characterization of the same.

199. Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 199 and on that basis denies the same. Footnote 5 contains no factual allegations as to which a responsive pleading is required. To the extent a response is required, Questcor denies the allegations in footnote 5.

200. Denied.

201. Denied.

202. Paragraph 202 states legal conclusions as to which no response is required. To the extent a response is required, Questcor respectfully refers the Court to the relevant regulations for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 202 and on that basis denies the same.

203. Questcor respectfully refers the Court to the relevant regulations for their actual language and complete contents and denies the United States' characterization of the same. Except as so stated, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 203 and on that basis denies the same.

204. Denied.

205. Denied.

206. Denied.

207. Questcor denies the allegations in the first sentence of Paragraph 207. Questcor is without knowledge or information sufficient to admit or deny the allegations in the second, third, and fourth sentences in Paragraph 207 and on that basis denies the same. Questcor further denies that it engaged in any violation of law.

208. Questcor admits that Acthar is sold in 5 milliliter vials. Except as so admitted, Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 208 and on that basis denies the same.

209. Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 209 and on that basis denies the same.

210. Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 210 and on that basis denies the same.

211. Denied.

212. Denied.

213. Denied.

214. Denied.

215. Denied.

216. Questcor is without knowledge or information sufficient to admit or deny the allegations in Paragraph 216 and on that basis denies the same. Questcor further denies that it engaged in any violation of law.

217. Denied.

218. Denied.

219. Denied.

220. Denied.

221. Denied.

222. Denied.

223. Questcor incorporates by reference its answers to Paragraphs 1 through 222 with the same legal force and effect as if fully set forth therein.

224. Denied.

225. Denied.

226. Denied.

227. Questcor incorporates by reference its answers to Paragraphs 1 through 226 with the same legal force and effect as if fully set forth therein.

228. Denied.

229. Denied.

230. Denied.

Questcor further denies each and every allegation contained in the Complaint, including headings, charts, graphs, and figures, except as expressly admitted and qualified above.

* * * * *

PRAYER FOR RELIEF

Questcor denies that the United States is entitled to the relief requested in its prayer for relief.

REQUEST FOR TRIAL BY JURY

The United States' request for trial by jury contains no factual allegations to which a response is required. To the extent a response is required, Questcor admits that the United States purports to demand a jury trial.

AFFIRMATIVE AND OTHER DEFENSES

Without undertaking any burden of proof not otherwise assigned to it by law, Questcor asserts the following affirmative and other defenses with respect to the claims the United States purports to assert in the Complaint.

FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

1. The United States fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

(No Causation)

2. Questcor's actions were not the proximate cause or cause in fact of any injury or loss, if any, alleged in the Complaint.

THIRD AFFIRMATIVE DEFENSE

(No Causation – Acts or Omissions by Third Parties)

3. Questcor's actions did not cause and could not have caused third parties to present false claims to federal healthcare reimbursement programs. The formulation and submission of the subject claims, and any damages alleged by the United States, are the result of independent and intervening acts or omissions committed by third persons over whom Questcor had neither control nor responsibility, and whose actions cannot be imputed to Questcor. If third parties submitted any materially false claims to federal healthcare

reimbursement programs for the purpose of getting a false claim paid or approved, such actions were not caused by Questcor.

FOURTH AFFIRMATIVE DEFENSE

(No False Statement)

4. Questcor did not make or use any materially false statements for the purpose of getting a false claim paid or approved by the federal government.

FIFTH AFFIRMATIVE DEFENSE

(No Violation of Anti-Kickback Statute)

5. Questcor's actions did not violate the Anti-Kickback Statute.

SIXTH AFFIRMATIVE DEFENSE

(No Scierter)

6. Questcor did not act knowingly or with reckless disregard. Instead, to the extent any of the actions alleged by the United States occurred, said actions were taken in good faith and not with any improper or illegal purpose, intent or knowledge.

SEVENTH AFFIRMATIVE DEFENSE

(Good Faith Reliance)

7. Questcor's actions were undertaken in good faith and/or in reasonable reliance upon regulatory interpretations and judgments by federal employees or officials upon whom Questcor was entitled to rely. Further, Questcor's actions constitute lawful, proper, justified and/or privileged conduct in accordance with the governing statutes and regulations.

EIGHTH AFFIRMATIVE DEFENSE

(Compliance with Law)

8. Questcor's actions fall within the guidelines established by the HHS-OIG, including those set forth in the Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623 (Nov. 22, 2005).

NINTH AFFIRMATIVE DEFENSE

(Reasonable Interpretation)

9. Questcor's actions were based on an objectively reasonable interpretation of the guidelines established by the HHS-OIG, including those set forth in the Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623 (Nov. 22, 2005). The relevant HHS-OIG guidelines were, at best, vague and ambiguous and did not warn the industry away from Questcor's interpretation.

TENTH AFFIRMATIVE DEFENSE

(Government Knowledge – No Scierter)

10. Representatives from the United States Department of Health and Human Services and its CMS, and individuals with authority to act on behalf of those agencies, knew that charities, including CDF, were providing co-pay assistance to Medicare Part D recipients, including through single-drug, single donor funds. These individuals further knew that the charities, including CDF, were funded, in part, by pharmaceutical companies, including Questcor. During the period in which Questcor made donations to CDF, Questcor was aware that the government was aware of and had approved CDF's patient assistance programs.

ELEVENTH AFFIRMATIVE DEFENSE

(Government Knowledge – No Materiality)

11. Representatives from the United States Department of Health and Human Services and its CMS, and individuals with authority to act on behalf of those agencies, knew that charities, including CDF, were providing co-pay assistance to Medicare Part D recipients, including through single-drug, single donor funds. These individuals further knew that the charities, including CDF, were funded, in part, by pharmaceutical companies, including Questcor. Despite the open and public nature of the alleged conduct and donations, and its knowledge of the co-pay assistance provided by CDF, including for Acthar, CMS authorized Part D Plan Sponsors to cover, and reimbursed Part D Plan Sponsors for, prescriptions for Acthar.

TWELFTH AFFIRMATIVE DEFENSE

(Violation of Excessive Fines and Due Process Clauses)

12. To the extent penalties and treble damages authorized under the False Claims Act so exceed any actual loss incurred by the Government as a result of any claims paid, such an award of civil penalties would violate the Excessive Fines Clause of the Eighth Amendment and the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution, and therefore would be void.

* * * * *

By alleging the matters set forth in these Affirmative Defenses, Questcor does not allege nor admit that it bears the burden of proof and/or persuasion with respect to any of these matters. Questcor presently lacks sufficient knowledge or information on which to form a

belief as to whether it may have additional available affirmative defenses. Questcor reserves the right to assert such additional affirmative defenses as may be appropriate.

* * * * *

WHEREFORE, Questcor respectfully requests that the Court (i) dismiss the United States' claims with prejudice; (ii) award Questcor the costs, disbursements and attorneys' fees incurred by it in defending this action; and (iii) grant such other and further relief as it may deem just and proper.

JURY TRIAL DEMAND

Questcor demands a jury trial on all issues so triable.

Dated: February 21, 2020

/s/ John N. Joseph

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Counsel for Defendant

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing was electronically filed with the Clerk of Court using the CM/ECF system, which automatically serves notification of such filing on all Counsel of Record, and is available for viewing and downloading from the CM/ECF system.

Date: February 21, 2020

/s/ John N. Joseph

John N. Joseph